p1/2 K031290

MAY 13 2003

510(k) Summary

Date
April 21, 2003

Submitter
Scient'x USA, Inc.
1015 Maitland Center Commons
Suite 106A
Maitland, FL 32751

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade name
EASYS Transverse Connection

Common name
Posterior spine system

Classification name
Spinal Interlaminal Fixation Orthosis
Spondylolisthesis Spinal Fixation Device System - class II
Pedicle Screw Spinal System - class II
888.3050 and 888.3070 (per 21 CFR section)

Indications
The EASYS Transverse Connection used with the ISOBAR Spinal System is intended for posterior, nonpedicle screw fixation of the noncervical spine/hook and sacral/iliac screw fixation to the noncervical spine/hook and sacral screw fixation to the T1-S1 spine.

Indications for use include:

- degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- tumor
- pseudoarthrosis
- failed previous fusion

The ISOBAR Spinal System is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The ISOBAR Spinal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Equivalent Device
This additional component is equivalent to the previous crosslink for the ISOBAR Spinal system in indications, usage and materials.

Device Description
The ISOBAR Spine System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar or sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusions.

As a pedicle screw system the ISOBAR Spinal System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The ISOBAR Spinal System consists of monoaxial and polyaxial pedicle screws (K990118, K991326, K013447 and K020245) rods, nuts and cross link members. It can be used for single or multiple level fixation. It also included single and double hooks (K013444 and K013440) used for posterior, nonpedicle screw fixation of the noncervical spine/hook and sacral/iliac screw fixation to the noncervical spine/hook and sacral screw fixation to the T1-S1 spine.

All components are manufactured from titanium alloy (Ti-6Al-4V) that conforms to ASTM F136.

The additional component that is the subject of this Special 510(k) submission is the EASYS Transverse Connection. Its purpose is to provide rigidity to the spinal construct similar to the crosslink cleared on K990118. It consists of a cross bar and two self locking jumpers. The jumper consists of a clamp and tightening screw.

Summary Nonclinical Tests
Testing per ASTM 1717 found that the EASYS Transverse Connection is as strong as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2003

Scient'x USA, Inc.
c/o Mr. J. D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K031290
Trade/Device Name: EASYS Transverse Connection
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle screw spinal system, Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: April 21, 2003
Received: April 23, 2003

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K031290

Device Name: EASYS Transverse Connection

Indications for Use:

EASYS Transverse Connection used with ISOBAR Spinal System Indications for Use

The EASYS Transverse Connection used with the ISOBAR Spinal System is intended for posterior, nonpedicle screw fixation of the noncervical spine/hook and sacral/iliac screw fixation to the noncervical spine/hook and sacral screw fixation to the T1-S1 spine.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

(Optional format 1-2-96) ____

for Mark N. Melkerson
(Division Sign-off)
Division of General, Neurological
and Restorative Devices

510(k) Number K031290